United States Senate

WASHINGTON, DC 20510

November 23, 2020

The Honorable Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We are continuing to conduct oversight of the U.S. Food and Drug Administration's (FDA) efforts to authorize potential treatments to patients suffering from COVID-19. On August 18, 2020, we requested information about the FDA's decision to issue and then subsequently revoke the Emergency Use Authorization (EUA) for the use of hydroxychloroquine (HCQ) and chloroquine (CQ) to treat COVID-19 patients.[1] The FDA's October 6, 2020 response did not address many of the issues we raised in our letter.

As we stated in our initial letter, we agree with your emphasis on utilizing every possible treatment option to treat or prevent COVID-19.[2] However, many licensed physicians remain deeply concerned with the FDA's approach to early treatment for COVID-19 outpatients. According to these physicians, it is a fundamental principle that the treatment to any infection is almost always most effective when taken during the early phase of the illness.[3] In this context, the FDA's lack of clarity and general inaction with regard to potential early home treatments risks delaying recovery for COVID-19 patients and contributing to increased hospitalizations and deaths.[4]

Several U.S. physicians have highlighted efforts in other countries to care for COVID-19 patients with inexpensive early treatments. These countries have considerably lower COVID-19 deaths per million population compared to those who offer no early treatments. These early treatments have assisted in "reducing the severity of symptoms, shortening the course of illness, and reducing the risks of hospitalization and death."[5] The most common approaches to early treatment are "off label" use of antivirals (hydroxychloroquine, ivermectin, favipiravir, combined with an antibiotic azithromycin or doxycycline), after five days, or if pulmonary symptoms develop, then oral corticosteroids are administered. Given the very high risks of thrombosis, antiplatelet and antithrombotic agents are used according to clinical judgement. Other countries have utilized at home treatments to prepare for and stem the pandemic. For example, favipiravir, an oral polymerase inhibitor that is similar to a pill form of remdesivir, is currently being used in 30 countries.[6] Another example is bromhexine,

[1] Letter from Senator Johnson, Senator Lee, and Senator Cruz, to Comm'r Stephen Hahn, U.S. Food & Drug Admin. (Aug. 18, 2020), https://www.hsgac.senate.gov/imo/media/doc/2020-08-18%20RHJ%20Letter%20to%20FDA%20on%20HCQ%20+%20CQ.pdf
[2] https://www.hsgac.senate.gov/imo/media/doc/2020-08-18%20RHJ%20Letter%20to%20FDA%20on%20HCQ%20+%20CQ.pdf
[3] Peter A. McCullough, *Why home treatment of COVID-19 with several drugs is crucial*, The Hill (Oct. 1, 2020, 11:30 AM), https://thehill.com/opinion/healthcare/518589-why-home-treatment-of-covid-19-with-several-drugs-is-crucial.
[4] *Id.*
[5] Letter from Acting Assoc. Comm'r Andrew Tantillo, U.S. Food & Drug Admin., to Senator Johnson, Chairman of Homeland Security & Governmental Affairs Comm. (Oct. 6, 2020), https://www.hsgac.senate.gov/imo/media/doc/2020-3977%20RESPONSE%20JOHNSON.pdf
[6] *Id.*

an inexpensive over-the-counter mucolytic with clinical efficacy in COVID-10 treatment; Bromhexine is being widely used outside of North America.[7] Unfortunately, both of these treatments are not available in the U.S.[8]

During the current emergency, we agree with the FDA's statement that the agency should act with the strongest sense of urgency.[9] Unfortunately, the lack of attention placed on early, home treatment for COVID-19 and the confusion caused by the FDA's EUAs have likely undermined the COVID-19 response. We believe the federal government should not stand in the way of informed decisions between patients and their physicians that could save American lives. We therefore respectfully ask the FDA to produce the following records or address the following issues with updated guidance or other appropriate documentation:

1. Please produce any and all updated guidance the FDA has provided to physicians and the public regarding early onset, at home treatments (clinically indicated, medically necessary, appropriate off-label administration) for COVID-19.
2. Please produce a specific updated review of the safety and efficacy of HCQ in the early ambulatory treatment of COVID-19.
3. In the FDA's EUA denial letter to the Henry Ford Hospital System, the FDA stated, "we conclude that the known and potential benefits of HCQ sulfate in disease prevention or treatment of early COVID-19 infections do not outweigh the known and potential risks for these proposed uses."[10] However, the majority of the studies cited by the FDA did not reach that conclusion. Please perform a contemporary analysis based upon the numerous outpatient studies of HCQ in the early treatment of COVID-19 and provide the results.
4. Please produce all documents and communications between or among employees, agents, or contractors of the FDA and employees from January 1, 2020 to the present referring or relating to treatment of COVID-19, including but not limited to hydroxychloroquine, chloroquine, remdesivir, etc.
5. The FDA rejected the Henry Ford outpatient EUA application for HCQ, stating that it required randomized controlled trial (RCT) evidence of benefit. Please provide documentation of this RCT requirement for EUA approval of medications.

Please produce this material as soon as possible, but no later than by 5:00 p.m. on December 7, 2020. If you have any questions about this request, please ask your staff to contact Shani Rosenstock and Josh McLeod of Senator Johnson's staff at (202) 309-7189. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
United States Senator

Michael S. Lee
United States Senator

[7] Peter A. McCullough, *Why home treatment of COVID-19 with several drugs is crucial*, The Hill (Oct. 1, 2020, 11:30 AM), https://thehill.com/opinion/healthcare/518589-why-home-treatment-of-covid-19-with-several-drugs-is-crucial.
[8] *Id.*
[9] *Id.*
[10] Letter from Director Peter Stein, U.S. Food & Drug Admin., to John McKinnon, Department of Medicine Henry Ford Hospital. (Aug. 2020), https://aapsonline.org/FDA-EUA-HF-rejection-letter.pdf

Ted Cruz
United States Senator

cc: The Honorable Alex M. Azar II
U.S. Department of Health and Human Services